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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,411	01/08/2001	Franco Lori	NIH061.1CP1C2	5460

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EXAMINER

CRANE, LAWRENCE E

ART UNIT PAPER NUMBER

1623

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/756,411	Applicant(s) Lori et al.	
	Examiner L. E. Crane	Group Art Unit 1623	

- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

Status

- ☒ Responsive to communication(s) filed on **-09/04/02 (amdt C & IDS#2)-**.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claims **--21-30--** are pending in the application. Claims **-9-19-** have been cancelled. Of the above claim(s) **--[]--** is/are withdrawn from consideration.
- ☐ Claim(s) **--[]--** is/are allowed.
- ☒ Claims **--21-30--** are rejected.
- ☐ Claim(s) **--[]--** is/are objected to.
- ☐ Claim(s) **--[]--** are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on **-[]-** are ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-[]-** is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119(a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-[]-**.
- ☐ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: **-[]-**.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). **--08--**
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-[]-**.

U.S. Patent Trademark Office

Office Action Summary

PTO-326 (Rev. 06/19/01)

S. N. 09/756,411

Paper No. **09**

Copy for ☒ **FILE** [] **APPLICANT**

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Claims 9-19 have been cancelled, no claims have been amended, and new claims 21-30* have been added as per the amendment filed September 4, 2002. Six Exhibits have also been received as attachments to the amendment.

5 *Claims originally submitted were numbered 20-29 but overlapped with claim number 20, now cancelled. As a consequence the claims newly added have been renumbered under the authority of 37 C.F.R. §1.126 as noted above.

Claims 21-30 remain in the case.

10 Claims 21-30 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

15 Claims 21-30 are directed to pairs of compounds, the specific chemical identities of which either have not been specified or have been only specified in part, and are therefore claimed more broadly than is supportable by the instant disclosed exemplification.

20 Applicant's arguments filed September 4, 2002 have been fully considered but they are not persuasive.

25 The noted claims have not met the written description standard of Regents of the University of California v. Eli Lilly (119F.3d 1559 at 1568; 43 USPQ2d 1398 at 1406 (Fed. Cir 1997)) which MPEP §2163 at page 2100-162, column 1, quotes as follows: "A definition by function alone 'does not suffice' to describe a coding sequence 'because it is only an

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indication of what the gene does, rather than what it is.” Applicant continues to rely on generic functional terminology including “an inhibitor of ribonucleotide reductase” and “an antiviral nucleoside phosphate analog other than a thymidine or cytidine analog” wherein the disclosure definition thereof does not overcome the functionality of the noted term.

Claims 21-30 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 21-30 are only enabled by the combination of hydroxyurea and 2',3'-dideoxyinosine. With only a single example of efficacy demonstrated, examiner is unable to agree that the single example that works is supportive of extrapolation to other examples which are only prospective without additional evidence in support of such an extrapolation. Examiner notes the opinions of other authorities, but must rely on US precedent including *Ex parte Balzarini et al.* 21, USPQ 2d 1892, 1894 (BPAI, 1991) which in its first opinion stands for the proposition that claims directed to medicinal treatments of diseases in highly unpredictable art areas are properly rejected under 35 U.S.C. §112, first paragraph as lacking adequate enablement, in the absence of sufficient test data in support of the efficacy of the alleged treatment. See MPEP at 2107.03 (p. 2100-44, col. 2, in the August, 2001 revision).

Applicant's arguments filed September 4, 2002 have been fully considered but they are not persuasive.

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Examiner has reviewed pages 24-25 and Table 7 at page 26 and, because of the repeated use of terms like "expected," has come to the conclusion that the disclosure of Table 7 is entirely prospective for all combination therapies except that of hydroxyurea plus ddI, a finding of
5 Malley et al. '161, PTO-892 ref. E.

Claims 21-30 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 Claims 21-30 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language. These claims are omnibus claims.

15 In each of claims 21-30 one or both of the active ingredients have not been specified with other than with functional language, and therefore each noted claim lacks properly defined metes and bounds because the ordinary practitioner cannot determine what is included or excluded, or what was included or excluded at the time of filing.

Applicant's arguments with respect to claims 9-19 have been considered but are moot in view of the new grounds of rejection.

20 The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ
25 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA

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1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

5 A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

10 Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

15 Claims 21-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-22 of U.S. Patent No. 6,046,175 (PTO-892 ref. H). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a binary composition which includes two active ingredients generically defined in a manner which includes the subject matter previously claimed.

Applicant's arguments filed September 4, 2002 have been fully considered but they are not persuasive.

20 Applicant has acknowledged the possible appropriateness of the instant rejection has not provided an appropriate terminal disclaimer.

25 Claims 21-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-8 of U.S. Patent No. 6,194,390 (PTO-892 ref. J). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a method of

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treating HIV in a human host wherein the active ingredients are defined generically in a manner which includes the subject matter of the previously patented claims.

5 Applicant's arguments filed September 4, 2002 have been fully considered but they are not persuasive.

Applicant has acknowledged the possible appropriateness of the instant rejection has not provided an appropriate terminal disclaimer.

10 Claims 21-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,521,161 (PTO-892 ref. E). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a method of treating HIV in a human host wherein the active ingredients are defined generically in a manner which includes the subject matter of the
15 previously patented claims.

Applicant's arguments filed September 4, 2002 have been fully considered but they are not persuasive.

Applicant has acknowledged the possible appropriateness of the instant rejection has not provided an appropriate terminal disclaimer.

20 Claims 21-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,736,527 (PTO-892 ref. G). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a method of
25 treating HIV in a human host wherein the active ingredients are defined

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generically in a manner which includes the subject matter of the previously patented claims.

Applicant's arguments filed September 4, 2002 have been fully considered but they are not persuasive.

5 Applicant has acknowledged the possible appropriateness of the instant rejection has not provided an appropriate terminal disclaimer.

Claims 21-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-8 of U.S. Patent No. 6,093,702 (PTO-892 ref. K). Although the
10 conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a binary composition which includes two active ingredients generically defined in a manner which includes the subject matter previously claimed.

15 Applicant's arguments filed September 4, 2002 have been fully considered but they are not persuasive.

Applicant has acknowledged the possible appropriateness of the instant rejection has not provided an appropriate terminal disclaimer.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of
20 the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of
25 the THREE-MONTH shortened statutory period, then the shortened

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statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at (703)-308-4624.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

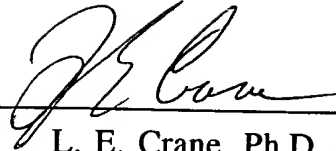
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LECrane:lec
09/19/02

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L. E. Crane, Ph.D., Esq.

Patent Examiner

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